K041778

AUG 3 1 2004

510(k) Summary

Sponsor Information:

Maxi-Aids
42 Executive Boulevard
Farmingdale, NY 11735
Elliot Zaretsky
Phone (631) 752-0521
Facsimile (631) 752-0689

Date Prepared:

June 25, 2004

Device Name:

Proprietary Name: Reizen Talking Blood Pressure Monitor, Model SF860T

Common/Usual Name: Blood pressure monitor

Classification Name: Noninvasive blood pressure measurement system (per 21 C.F.R. § 870.1130)

Device Description, Intended Use, and Technological Characteristics:

The Reizen Talking Blood Pressure Monitor SF860T measures systolic and diastolic blood pressures and pulse rate. It uses the oscillometric method. It is indicated for use by adults (those 18 years of age and older) at home or in another outpatient setting. It has the same technological characteristics as the predicate device.

Predicate Device:

A&D Medical LifeSource Talking Digital Blood Pressure Monitor, Model UA-767T

Performance Data:

The device has been certified as meeting the standards of the ISO 9001/ISO 13485 Quality System Standard. Further, it has been certified as complying with the applicable requirements of the European Union Medical Devices Directive (93/42/EEC). The device also passed testing to show conformance with the ANSI/AAMI SP10 Standard.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 1 2004

Maxi Aids, Inc.
c/o Mr. Wayne H. Matelski
1050 Connecticut Avenue
Washington, DC 20036-5339

Re: K041778
Trade Name: Reitzen Talking Blood Pressure Monitor, Model SF860T
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: June 28, 2004
Received: July 1, 2004

Dear Mr. Matelski :

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041778

Device Name: Reizen Talking Blood Pressure Monitor, Model SF860T

Indications For Use:

The device measures systolic and diastolic blood pressures and pulse rate. It uses the oscillometric method. It is indicated for use by adults (those 18 years of age and older) at home or in an outpatient setting.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogden for

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041778